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<b>(21) International Application Number:</b> PCT/US98/10869 <b>(22) International Filing Date:</b> 26 May 1998 (26.05.98) <b>(30) Priority Data:</b> 08/881,853      24 June 1997 (24.06.97)      US <b>(71) Applicant (for all designated States except US):</b> FUISZ TECHNOLOGIES LTD. [US/US]; 14555 Avion at Lakeside, Chantilly, VA 20151 (US). <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> CHERUKURI, S., Rao [US/US]; 10241 Britten Ford Drive, Vienna, VA 22182 (US). YANG, Robert, K., Ph., D. [US/US]; Apartment 2-C, 138-10 Franklin Avenue, Flushing, NY 11355 (US). ZAMUDIO-TENA, Jose, F. [MX/US]; Courtyard IV, 2459 Glengyle Drive, Vienna, VA 22181 (US). BAYARD, Claude, A. [US/US]; 2301 S. Jefferson Davis Highway, Arlington, VA 22202 (US). SIRIS, Supapong [US/US]; 13720 Rosetree Court, Chantilly, VA 20151 (US). <b>(74) Agents:</b> LEVIS, John, F. et al.; Fuisz Technologies Ltd., 14555 Avion at Lakeside, Chantilly, VA 20151 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> POSITIVE HYDRATION METHOD OF PREPARING CONFECTIONERY AND PRODUCT THEREFROM  <b>(57) Abstract</b>  The present invention is a new method of making a confectionery mass, such as a nougat, by hydrating sufficiently to form the mass without the need for cooking to drive off moisture. The present invention also includes a product prepared by positively hydrating a mixture of confectionery ingredients including a hydrobinding component and a saccharide-based material.		

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## POSITIVE HYDRATION METHOD OF PREPARING CONFECTIONERY AND PRODUCT THEREFROM

This is a continuation-in-part of co-pending U. S. application Serial No. 08/773,025 filed December 24, 1996, which is a continuation-in-part of U.S. Patent 5,587,198.

### Background of the Invention

The present invention relates to the art of unique delivery systems for comestibles, especially to confectionery manufacturing and particularly to novel methods of making a functionalized confectionery mass which do not require cooking to dehydrate and products therefrom. More particularly, the invention relates to comestible delivery systems, uncooked confectioneries and nougats, and methods for making same.

It is generally considered a necessity in the art of preparing food or drug delivery systems like confectionery masses such as nougats to use water as a mixing medium and source of hydration for ingredients. Specifically with respect to nougats, a typical recipe calls for soaking egg albumen in water over a period of time, such as overnight, in order to fully hydrate the protein. Following hydration the egg albumen is stirred and strained before being beaten into a stiff foam. Other ingredients such as sugar, honey, and corn syrup are separately cooked with water to a relatively high cooking temperature of from about 135°C to about 138°C to achieve the necessary interaction among the ingredients. The cooked mixture is then poured into the egg and beaten with a nougat mixer, which is similar to a marshmallow mixer but generally more robust. Additional parts of sugar and other ingredients must then be added and the mixture beaten or stirred over a hot water bath. This conventional nougat preparation method requires cooking the ingredients and using a significant amount of water to serve as a mixing medium and source of hydration. The amount of water used is much larger than that which would permit the formation of the solid nougat. Consequently, the excessive moisture must be driven off as much as possible to achieve the structural integrity and consistency necessary for the end product.

Conventional art processes require excessive amounts of water to provide a

5 mixing medium and to hydrate the components. With respect to hydration, water is supplied in more than sufficient quantity to ensure that specific ingredients are wetted and functionalize. With respect to use of water as a mixing medium, once again an excessive amount of moisture is generally used so that ingredients can be contacted by suspension or dissolution in the medium. The overall process requires the use of far more moisture than is actually required to provide solubility of the ingredients. Unless the water is forcibly removed, the process will result in an incoherent product having no significant structural integrity.

10 A consequence of using excessive water to hydrate and as a mixing medium is the artisan must then reduce the unwanted additional moisture. This is generally undertaken by a combination of mixing and boiling to drive off the moisture and bring the mass to proper viscosity and consistency. This process, however, can be highly energy-inefficient and very costly as it requires heat, excessive handling of nougat masses, flashing off of some critical fluids, and an inability to incorporate heat sensitive materials, as well as a less desirable overall stability of the product. Moreover, it is not effective in completely eliminating a substantial amount of the moisture contained in the confectionery mass.

15 One of the unwanted results of inefficient dehydration is that water remains as a separate phase in the end product. This water is not bound to other ingredients and can be referred to as free moisture or unbound water. Free moisture can detract from the end product because it weakens the structural integrity and/or reduces the quality of organoleptic perception. Moreover, excessive free moisture results in higher water activity, and thereby provides an environment in which microorganisms can grow. Microbiological growth in food products has also been used to measure the existence of free moisture.

20 Free moisture has been identified in food art by the term water activity. Water activity is defined as the ratio of the vapor pressure of water in an enclosed chamber containing a food to the saturation vapor pressure of water at the same temperature. Water activity is an indication of the degree to which unbound water is found and, consequently, is available to act as a solvent or to participate in destructive chemical and

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microbiological reactions.

Many food preservation processes attempt to eliminate spoilage by lowering the availability of water to microorganisms. Reducing the amount of free moisture or unbound water also minimizes other undesirable chemical changes which can occur in foods during storage. The processes used to reduce the amount of unbound water in foods include techniques such as concentration, dehydration, and freeze-drying. These processes require intensive expenditure of energy and are not cost efficient.

The present invention overcomes the difficulties set forth above as well as other difficulties generally associated with the prior art. In particular, both the necessity of cooking the confection to obtain desired physical properties and using excessive water to mix and hydrate one or more ingredients is eliminated, and the method and product of the invention are obtained without any need for dehydration. Heating at high temperatures and mixing to drive off excessive moisture are no longer required. Consequently, the detrimental heat history generally associated with energy-intensive procedures is also eliminated. Separation of the water from the resulting product is avoided and the lowered water activity results in a product having superior physical, storage, and organoleptic properties with reduced microbial growth problems.

#### **Summary of the Invention**

The present invention is a method of making a unique food and drug delivery system, and especially a novel confectionery delivery system, especially a nougat, by a positive hydrating step and without the need for dehydrating in order to produce the confectionery mass. The present invention also includes the product resulting from the new method of preparation.

In one preferred embodiment, a saccharide-based component is combined with a hydrated hydrobinding component.

A primary part of the saccharide-based component is a saccharide material such as sucrose, corn syrup solids, polydextrose, and mixtures thereof. A preferred saccharide-based ingredient is polydextrose. Other highly preferred saccharide materials include sucrose and corn syrup solids. Maltodextrin is also highly desirable, as well as

mixtures of any of the foregoing. (A saccharide ingredient can also be included as part of the hydrobinding component, as for example, a sweetener.)

The hydrobinding component can include a proteinaceous material such as a gelatin, or a food grade gum such as gum arabic, carrageenan, locust bean gum, guar gum, and mixtures thereof. One preferred hydrobinding component includes a mixture of a gelatin and gum arabic. Another preferred hydrobinding ingredient includes a mixture of carrageenan, locust bean gum, and a crosslinking agent. Generally, the gelatin and/or food grade gum imparts viscoelasticity to the confectionery mass, possibly as a result of cross-linking in these materials.

In another embodiment, the hydrobinding component can also be aerated, preferably in the presence of an aerating agent, prior to or after combining it with the saccharide-based component. Aerating agents include, among other things, egg whites, soy protein, and combinations thereof.

Other ingredients can also be included in conjunction with the hydrobinding component, including oleaginous materials, such as hydrogenated vegetable oils, emulsifiers, and mixtures thereof. Preferably, the hydrobinding component is further employed with a wetting agent or humectant, such as polyol like glycerin or other commercially available material having similar functionality.

It is further contemplated that active ingredients can be included in the confectionery mass which is formed as a result of the present invention. The active ingredients are typically ones which are intended to produce a biological and/or chemical response in the body. The active ingredients can be quite varied, and a non-exhaustive list has been set forth hereinbelow. Especially preferred actives include antacid materials or bioassimilable sources of calcium.

In another preferred embodiment of the present invention a nougat mass is prepared which has a frappe consistency and is made with nutritional ingredients so that a health product can be produced. In particular, vegetable and/or fruit components can be added to provide a nutritious food product. If desired, a product having the minimum daily nutritional requirements can be produced. The recommended human adult dietary

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serving of nutrients is defined by the Consumer Affairs Division of the United States Food and Drug Administration. In fact a health bar has been prepared which contains the nutritional equivalent of up to five (5) recommended human adult dietary servings of vegetable and/or fruit. Furthermore in this regard, ingredients which have strong olfactory characteristics, e.g., aroma and flavor, can be treated to enhance control of potency before incorporating into a health product prepared in accordance with the invention.

The product resulting from the present invention is unique because it requires no cooking and no dehydration by traditional heating at high temperatures to produce, and has substantially no phase separation of moisture. The only moisture present is an amount sufficient to functionalize the mass. Thus, the product can be prepared without cooking. As herein further described, the product can also be prepared using low or high shear mixing, i.e. with no flash-flow processing is required.

It is well known that free moisture in food products can detract from the product. Free moisture has been identified in the art by the use of water activity. In the present invention, the water activity is not greater than about 60% ERH, and is preferably not greater than about 55% ERH.

Another measure of free moisture in foodstuffs is the amount of biological growth within the composition. In the present invention, the biological activity is less than about 100 ppm, preferably less than about 25 ppm, and most preferably less than about 10 ppm.

The present invention also provides the ability to formulate confectionery masses with a significantly reduced fat and calorie content. This result is quite unexpected, since fat has traditionally been used to assist in functionalizing food masses by providing internal lubrication without water.

Other features of the method of the invention include improved processing, intimate mixing and enhanced dispersion of dissimilar ingredients. The final product furthermore exhibits improved content uniformity and improved taste perception qualities. In fact, consumers consistently rate the product of the invention higher than many commercially-prepared similar formulations for such qualities as firmness, flavor,

bite, sweetness, chewiness, melt characteristics, stickiness, juiciness, freedom from grit, and aftertaste. Overall, the formulated confectionery delivery system herein described is more palatable than many of the current products available in the art.

For a better understanding of the present invention, together with other and further objects, reference is made to the following description taken in conjunction with the examples, and the scope is set forth in the appended claims.

### Detailed Description of the Invention

The method for making confectionery-mass delivery systems in accordance with the present invention includes combining a saccharide-based component and a hydrobinding component, the latter component being hydrated sufficiently to provide controlled water delivery to the saccharide-based component and/or other ingredients. Controlled water delivery means delivery of water in an amount and at a rate which is sufficient to provide internal viscosity and cohesivity to the saccharide-based component. The word hydrated as used in the term hydrated hydrobound component herein means containing sufficient water to provide the requisite controlled water delivery.

The system created by the combination of the present invention is a water-starved system, which means that the system has only enough moisture to bind the ingredients together and provide internal lubricity. Since the ingredients are competing for moisture due to enhanced wettability, there is virtually no free moisture available to separate from the mass.

In one embodiment of the invention, the saccharide-based component can be advantageously provided in the form of a shearform matrix, as that term is defined hereunder, as a shearform matrix has significantly enhanced wettability because of a randomized structure resulting from flash-flow processing. Shearform matrix refers to the product prepared by a method of flash-flow processing, a method which mixes and conditions ingredients for intimate contacting and enhanced hydration described, for example, in US 5,587,198. The invention can benefit from subjecting the saccharide-based component to such flash-flow processing to provide a saccharide based shearform matrix. The hydrobinding component can, if desired, also be subjected to



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flash-flow processing before hydrating. The hydrobinding component can also be aerated, preferably in the presence of an aerating agent, before or after combining with the shearform matrix.

One embodiment of the present invention also includes flash-flow processing of certain ingredients prior to combining with other ingredients as set forth hereinabove. This is referred to as pre-flash-flow processing. Flash-flow processing and pre-flash-flow processing results in increased surface area and increased solubility of the ingredients subjected thereto, and contributes to actual binding of the ingredients to each other.

It may also be extremely desirable to utilize high or low shear mixing, hereinafter set forth, instead of flash flow processing, to pre-mix the major ingredients prior to combining with one another. It can also be highly preferred to use the aforesaid high or low shear mixing to mix the final feedstock containing the saccharide-based component and the hydrobinding agent so as to yield the confectionery delivery system herein set forth.

It is also within the scope of the invention to utilize flash-flow processing (or pre-flash-flow processing) and shear mixing in the preparation of the same final product. Thus, for example, the saccharide-based component could be first prepared by flash-flow, and then combined with the hydrating component by shear mixing.

As that term is used herein, high shear mixing refers to relatively intensive mixing action concentrated in a localized area. The high speed impact of mixing mechanisms such as blades or choppers results in shearing action. This in turn creates localized high shear force and a fluidizing effect at the point of contact, which causes particular scale diffusion and disagglomeration and faster mixing in a relatively small area of the entire mixing volume. High shear mixing may also result in increased temperature at the point of impact of the shearing apparatus with the mix, thereby further contributing to the effective mixing action.

High shear mixing should be contrasted with low shear mixing in which the main action of mixing is due to the relative motion of a much larger volume of mix being circulated by the spinning or churning action of a lower impact type mechanism, such as a

paddle-blade typically found in a Sigma or Hobart mixer. Whenever high or low shear mixing is utilized to produce the functionalized confectionery mass of the present invention, the resultant product can be referred to as both uncooked and unspun.

As noted, the present invention provides a method and composition for preparing a functionalized confectionery mass without the use of excess water. Functionalization of a confectionery mass means providing the ingredients with sufficient internal cohesivity to be handled without losing its integrity as a mass. In order to be handled in the context of functionalization, the mass must also possess internal lubricity which permits inter- and intra-particle movement without loss of cohesiveness. Functionalized food masses have been described as having the consistency of a dough or paste, or as chewy, etc. However, the present invention is not to be limited by any short-hand description of the consistency.

Functionalization of food masses has in the past relied upon the use of significant amounts of added fat, but the present invention enables the artisan to functionalize a confectionery mass without need for added fat if so desired. Functionalization is achieved in the present invention by using certain ingredients, as specified herein. Nonetheless, selected amounts of fat may be added to obtain a confection having desirable perceived texture and/or flavor characteristics.

In the present invention, a hydrobinding component is used to provide a functionalized hydrobound confectionery mass. A functionalized hydrobound confectionery mass as used herein is a functionalized mass of confectionery ingredients which contains substantially no excessive free moisture or unbound water. A functionalized hydrobound confectionery mass of the present invention does not require dehydration, e.g., by cooking at high temperatures, to remove excess water. The method of the invention, therefore, is substantially more efficient than previously known methods. Less energy costs are expended in the methods herein set forth, while the resulting product is a markedly improved confectionary delivery system.

While applicants do not wish to be bound by theory, it is believed that water is tightly bound to surface polar sites through chemisorption. These sites may include the hydroxyl groups of hydrophilic materials such as proteins, gums, starches, and sugar.

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Regardless of the actual mechanism, however, this phenomenon is referred to herein as hydrobinding.

A hydrobinding component is an ingredient which imbibes, delivers and maintains water in an amount sufficient to functionalize the resulting mass. The water which is hydrobound does not separate and become a separate phase. A hydrobinding component cooperates with other ingredients to deliver and maintain water sufficient to functionalize the mass of ingredients, including those ingredients which have been subjected to flash-flow processing. The invention is furthered if flash-flow processing is used to prepare other ingredients for use in the confectionery mass. Flash-flow processing not only ensures intimate mixing of ingredients without the use of water as a medium, but also conditions the ingredients for wetting with a minimum of water. It has now been further found that shear mixing, and preferably high shear mixing, can achieve the beneficial results of flash-flow processing, but without the extra time and cost associated therewith.

Thus, a hydrobinding component can be hydrated and mixed with a shearform matrix (i.e., ingredients which have been subjected to flash-flow processing) or shear mixed with the ingredients (making up the saccharide-based feedstock) to form a functionalized hydrobound confectionery-mass delivery system. After combining the hydrated hydrobinding component and the additional ingredients, moisture is readily imbibed and disseminated throughout the non-hydrated components and/or ingredients. Unlike prior art methods and confectionery compositions, additional moisture is not required to form a hydrated mixture. Thus, excess water is not present in the resulting mass.

The hydrobinding component and saccharide-based component, acting in concert with one another, capture or bind sufficient moisture to functionalize the total mass. The ingredients capture the moisture by some mechanism as yet unelucidated, possibly physically, chemically, and/or even biologically. Whatever the binding mechanism may be, water is held and made available for absorption by the remainder of the ingredients. The addition of considerable excess water is thus avoided, as is cooking to subsequently

drive off the added moisture.

Hydrobinding ingredients useful in the present invention include, for example, proteinaceous materials known to those skilled in the art, and preferably gelatins of various grades and types. Also preferred are food grade gums such as gum arabic, carrageenan, guar gum, and locust bean gum, and mixtures thereof. Hydrobinding ingredients comprising a mixture of components are desirable in some situations. Highly preferred hydrobinding ingredients include, for example, a mixture of gelatin and gum arabic, or a mixture of carrageenan and locust bean gum with a crosslinking agent, such as potassium citrate or potassium chloride, which induces crosslinking between these materials. These mixed hydrobinding materials are advantageous not only for their hydrobinding capacities, but also because they impart viscoelasticity to the resulting confectionery. It is possible that crosslinking in these materials contributes to their desirable physical properties. The hydrobinding material can also benefit from inclusion of a wetting agent or humectant such as a polyol known in the art, desirably glycerin, or other functionally similar materials which are commercially available.

The hydrobinding component will comprise about 0.5-20% of the comestible delivery system of the invention. Preferably, the hydrobinding component will be within the range of about 5-15%, and even more desirably within the range of about 5-10%. Of the foregoing hydrobinding component, water will comprise about 30 - 80% thereof, and preferably about 40 - 70% of the hydrobinding component. The proteinaceous material or the gum, or combination thereof, will make up about 0.5 to 60% of the hydrobinding component, and more preferably be within the range of about 3 to 50%, more desirably about 5 to 20% (unless otherwise set forth, all %s herein are percentages by weight, or weight percent). Another material which may be included as part of the hydrobinding component is a wetting or softening agent, such as a polyol, preferably glycerin, which may be included in amounts equal to about 0 - 15%, preferably about 0.1 - 10% of the composition of the invention, even more desirably about 5-10%. The glycerin (or other selected material) can also function as a humectant, and thereby keep moisture in the system.

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It is also within the scope of the invention that ingredients which are used in the hydrobinding component may instead be added as part of the saccharide-based component. Thus, gelatins and food grade gums such as gum arabic, carrageenan, guar gum, locust bean gum, etc., can be used to prepare the saccharide-based component, e.g., by being included in the feedstock used to prepare that component.

The invention also employs a saccharide-based material as another major component (the hydrobinding material being the first major component). The saccharide-based material can include any of a large variety of saccharide materials, such as small sugars, e.g., dextrose, sucrose, fructose, etc., and larger saccharides such as corn syrup solids and polydextrose, as well as mixtures of two or more of these materials.

Corn syrup solids are highly preferred for use as the saccharide-based material in the composition of the invention. Corn syrup solids are commonly known as maltodextrins. Maltodextrins are composed of water soluble glucose polymers obtained from the reaction of the starch with acid or enzymes in the presence of water. The hydrolysis reaction produces a carbohydrate mixture of saccharides having a controllable dextrose equivalence (D.E.), commonly a D.E. of less than 20. When the hydrolysis is permitted to proceed to an extent sufficient to produce a D.E. of greater than 20, the FDA calls the resulting materials corn syrup solids.

Polydextrose is a non-sucrose, essentially non-nutritive, carbohydrate substitute. It can be prepared from polymerization of glucose in the presence of polycarboxylic acid catalysts and polyols. Generally, polydextrose is known to be commercially available in three forms: Polydextrose A and Polydextrose K, which are powdered solids, and Polydextrose N supplied as a 70% solution. Each of these products can also contain some low molecular weight components, such as glucose, sorbitol, and oligomers.

Sugars can also be used as saccharide-based materials according to the invention. Sugars are those substances which are based on simple crystalline mono- and di-saccharide structures, *i.e.*, based on C<sub>5</sub> (pentose) and C<sub>6</sub> (hexose) sugar structures. Sugars include dextrose, sucrose, fructose, lactose, maltose, etc., and sugar alcohols such as sorbitol, mannitol, maltitol, etc.

Typically, the foregoing saccharide-based component can comprise about 30 - 99.5% of the comestible delivery system according to the embodiments herein set forth. Preferably, there will be about 40 - 75% of this component present, and even more desirably about 50-70% present. In addition, those skilled in the art may discover a higher or lower percentage of the saccharide-based component, or other ingredients herein set forth, will produce a suitable final product, depending upon the final characteristics, *e.g.* texture, mouth feel, product consistency, etc., which are desired. A highly preferred saccharide-based material will comprise a mixture of corn syrup solids and sucrose in a ratio of approximately 50/50 or 40/60.

Other materials which can be incorporated into the material of the invention, to enhance its appearance, taste, texture, and other perceptions of the consumer, include, for example, flavors, sweeteners, colorants, surfactants or emulsifiers, and fats or oils. Any one or a combination of more than one of the foregoing may comprise from about 0 - 20% of the confectionery mass, and more desirably be within the range of about 5 - 10% or even up to 15% of the comestible mass.

Flavors may be chosen from natural and synthetic flavoring liquids. An illustrative list of such agents includes volatile oils, synthetic flavor oils, flavoring aromatics, oils, liquids, oleoresins or extracts derived from plants, leaves, flowers, fruits, stems and combination thereof. A non-limiting representative list of examples includes citrus oils such as lemon, orange, grape, lime, and grapefruit, as well as fruit essences including, for example, apple, pear, peach, grape, strawberry, raspberry, cherry, plum, pineapple, apricot, or other fruit flavors.

Other useful flavorings include, for example, aldehydes and esters such as benzaldehyde (cherry, almond), citral, *i.e.*, aliphacitral (lemon, lime), nerol, *i.e.*, betacitral (lemon, lime) decanal (orange, lemon), aldehyde C<sub>8</sub> (citrus fruits), aldehyde C<sub>9</sub> (citrus fruits), aldehyde C<sub>12</sub> (citrus fruits), tolyl aldehyde (cherry, almond), 2,6-dimethyloctanal (green fruit), and 2-dodecenal (citrus, mandarin), mixtures thereof, and the like.

Other flavorings may include whole and partial fruits and nuts, peanut butter,

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candy bits, chocolate chips, bran flakes, etc.

Sweeteners may be added to the comestible delivery system of the invention.

These may be chosen from the following non-limiting list: glucose (corn syrup), dextrose, invert sugar, fructose, and mixtures thereof (when not used as a carrier); saccharin and its  
5 various salts such as the sodium salt; dipeptide sweeteners such as aspartame; dihydrochalcone compounds, glycyrrhizin; Stevia Rebaudiana (Stevioside); chloro derivatives of sucrose such as sucralose; sugar alcohols such as sorbitol, mannitol, xylitol, and the like. Also contemplated are hydrogenated starch hydrolysates and the synthetic sweetener 3,6-dihydro- 6-methyl-1-1,2,3-oxathiazin- 4-one-2,2-dioxide, particu- larly  
10 the potassium salt (acesulfame-K), and sodium and calcium salts thereof. Other sweeteners may also be used. The sweeteners are added in amounts equal to about 0 – 10% of the composition, and preferably about 0.1 – 5%.

Surfactants or emulsifiers may also be included in the composition of the invention. These may be any food grade emulsifying material, for example, lecithin or  
15 other phospholipid material, monoglycerides and/or diglycerides, and mixtures thereof in amounts of from about 0 – 3%, more desirably about 0.1 – 1%.

Fats may also be included in the composition, and these can include partially or entirely unsaturated fats such as palm oil and cocoa butter. Hard fats having melting points above body temperature (37°C), and soft fats having a melting point of about or  
20 below body temperature, can be used alone or in combination. The texture and mouth feel of the resulting confection can be influenced by selecting the types and amounts of fats included in the saccharide-based component. Fats marketed under such trade names as Durem and Paramount have been found to be useful. Those skilled in the art will find that fats are optional as part of the composition of the invention, and may be eliminated  
25 altogether if so desired. Thus, fats will comprise about 0 - 10% of the product herein set forth, preferably less than about 7%, and even more preferably less than about 5%.

Additional materials which can be incorporated into the composition include, for example, biologically active ingredients such as medicinal substances, e.g. drugs, pharmaceuticals and antacids. These are referred to herein as active ingredients. Active

ingredients may make up from about 0 - 50% of the product of the invention, and may be more depending upon the needs and abilities of those skilled in the art. It is preferred, however, to include up to about 40% of active substance in the compositions set forth herein.

5 As active ingredients, the medicinal substances capable of incorporation and delivery according to the invention are extremely varied (those skilled in the art may conceive of others than those herein described, and these are certainly within the scope of the invention). An exemplary, non-limiting list of such medicinal substances includes: antitussives, antihistamines, decongestants, alkaloids, mineral supplements, laxatives,  
10 vitamins, e.g. vitamin D3, antacids, ion exchange resins, anti-cholesterolemics, anti-lipid agents, antiarrhythmics, antipyretics, analgesics, appetite suppressants, expectorants, anti-anxiety agents, anti-ulcer agents, anti-inflammatory substances, coronary dilators, cerebral dilators, peripheral vasodilators, anti-infectives, psycho-tropics, antimanics, stimulants, gastrointestinal agents, sedatives, antidiarrheal preparations, anti-anginal  
15 drugs, vasodialators, anti-hypertensive drugs, vasoconstrictors, migraine treatments, antibiotics, tranquilizers, anti-psychotics, antitumor drugs, anticoagulants, antithrombotic drugs, hypnotics, anti-emetics, anti-nauseants, anti-convulsants, neuromuscular drugs, hyper- and hypoglycemic agents, thyroid and antithyroid preparation, diuretics, antispasmodics, uterine relaxants, mineral and nutritional additives, antiobesity drugs,  
20 anabolic drugs, erythropoietic drugs, antiasthmatics, cough suppressants, mucolytics, anti-uricemic drugs, and mixtures thereof.

Analgesics include, for example, aspirin, acetaminophen, and acetaminophen plus caffeine.

25 Other preferred drugs for other preferred active ingredients for use in the present invention include, for example, antidiarrheals such as IMMODIUM AD®, antihistamines, antitussives, decongestants, vitamins, and breath fresheners. Also contemplated for use herein are anxiolytics such as XANAX®; antipsychotics such as clozaril and HALDOL®; non-steroidal anti-inflammatories (NSAIDs) such as VOLTAREN® and LODINE®; antihistamines such as SELDANE®, HISMANAL®, RELAFEN®, and TAVIST®;



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antiemetics such as KYTRIL® and CESAMET®; bronchodilators such as BENTOLIN®,  
PROVENTIL®; antidepressants such as PROZAC®, ZOLOFT®, and PAXIL®;  
antimigraines such as IMIGRAN®, ACE-inhibitors such as Vasotec, Capoten and Zestril;  
anti-Alzheimer's agents, such as NICERGOLINE; and Ca<sup>H</sup>-Antagonists such as  
5 PROCARDIA®, ADALAT®, and CALAN®.

The popular H<sub>2</sub>-antagonists which are contemplated for use in the present  
invention include cimetidine, ranitidine hydrochloride, famotidine, nizatidine, ebrotidine,  
mifentidine, roxatidine, pisatidine and aceroxatidine.

Other active ingredients include antiplaque medicaments and medicaments for  
10 veterinary use.

Especially preferred active ingredients contemplated for use in the present  
invention are antacids, H<sub>2</sub>-antagonists, and analgesics. For example, antacid dosages can  
be prepared using the ingredients calcium carbonate (CaCO<sub>3</sub>), either alone or in  
combination with magnesium hydroxide, and/or aluminum hydroxide. Moreover,  
15 antacids can be used in combination with H<sub>2</sub>-antagonists.

Active antacid ingredients include, but are not limited to, aluminum hydroxide,  
dihydroxyaluminum aminoacetate, aminoacetic acid, aluminum phosphate,  
dihydroxyaluminum sodium carbonate, bicarbonate, bismuth aluminate, bismuth  
carbonate, bismuth subcarbonate, bismuth subgallate, bismuth subnitrate, calcium  
20 carbonate, calcium phosphate, citrate ion (acid or salt), amino acetic acid, hydrate  
magnesium aluminate sulfate, magaldrate, magnesium aluminosilicate, magnesium  
carbonate, magnesium glycinate, magnesium hydroxide, magnesium oxide, magnesium  
oxide, magnesium trisilicate, milk solids, aluminum monobasic or dibasic calcium  
phosphate, tricalcium phosphate, potassium bicarbonate, sodium tartrate, sodium  
25 bicarbonate, magnesium aluminosilicates, and tartaric acids and salts.

Calcium supplement products can also be prepared by incorporation of a  
bioassimilable calcium source in the comestible delivery system confectionary of the  
invention. Preferably, the calcium source is calcium carbonate, but other sources of  
calcium capable of absorption or bioassimilation can be employed, including finely

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divided bone meal or oyster shell materials and the like. The calcium-containing material is preferably very finely divided so as not to impart any unnecessary chalkiness or other unpalatable characteristic to the confection. Finely ground calcium materials are commercially available, e.g., from Specialty Minerals, for use either in the antacid products or calcium supplement products. In one preferred embodiment of the invention, a calcium supplement product is prepared which incorporates 500 mg. Of bioassimable calcium, along with 200 I.U.'s of vitamin D3 into a single dosage form of the final product, which represents 50% of the RDA of those nutrients.

One of the advantages of the present invention is that a large proportion of the product can be displaced by a bulky material such as calcium sources. For example, up to about 25-35% or even more of the total weight of the resulting product can be an added bioassimilable calcium source, without imparting undesirable taste or texture to the product. In fact, the product according to several embodiments of the invention exhibits improved taste and texture characteristics as compared with similar commercially-available products. "Improved" means that individual consumers rate the product overall to be superior when such characteristics as firmness, flavor, bite, sweetness, chewiness, melt characteristics, stickiness, juiciness, freedom from grit, and aftertaste are analyzed.

Other bulky materials can also be included, e.g., fiber and other vegetable and fruit materials. Of course, useful comestible delivery systems can also be produced wherein as little as only a trace amount of the total weight of the product is a deliverable active ingredient.

Another component which can be included in products made in accordance with the present invention is a nutritional component. A nutritional component can include ingredients which have vitamins and minerals required to maintain good health. A health bar product has been prepared in accordance with the present invention which includes a dry residue of whole vegetables and/or fruits. In fact, a health bar product has been made which includes the nutritional equivalent of up to five (5) times the U.S. recommended human adult dietary serving of vegetables and/or fruit by incorporation of the dry residue of such fruits and vegetables. Sources of minerals and fiber can also be included.

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A preferred embodiment of the nutritional form of the product contemplates treating ingredients having strong olfactory characteristics, e.g., flavor and aroma, to reduce such characteristics. For example, dry residue of spinach and broccoli have been treated by heating in the presence of yogurt powder and a small amount of moisture to drive off strong aroma and flavor notes. This technique conditions such ingredients for incorporation in a health product without detracting from the overall smell and taste of the product. It has been found that the above technique is particularly effective for preparing a nutritional health bar product.

The hydrobinding component, e.g., the gelatin and/or gum, can be aerated, preferably in the presence of an aerating agent, before or after being combined with high shear processed components. Preferred aerating agents include egg whites and soy protein. Aerating agents are desirably added in amounts within the range of about 0 - 5%, more desirably 0.1 - 3%.

The products resulting from the present invention are unique, in part because they require no dehydration to produce, i.e., the product can be prepared without cooking. Moreover, there is substantially no separation of moisture in the resulting product. The only moisture present is an amount sufficient to functionalize the mass. No excess water is thus present.

The hydrobound system of the present invention is a mass which has been hydrated by adding moisture to provide hydrocolloidal stability, but which does not have measurable free water, e.g., syneresis is substantially halted. Syneresis refers to as the phenomenon of separation of water from a mass of material as a distinct phase. When the moisture is so minimal in a mass or sufficiently bound to other components in the mass that phase separation does not occur, syneresis is stopped or halted. When syneresis occurs, free water is available within the system. Free water is generally unwanted in confectionery products of the type disclosed herein because of product deterioration and micro-organic growth. A correlation between free water and water activity has been made as a measure of product stability.

Many properties of foods are affected by the content and nature of water which

they contain. Water participates in mass transfer and chemical reactions where it assumes a major role in determining physical and chemical content of foods. The production of a new food must almost inevitably confront the nature of water if the final product is to be stabilized with regard to nutritional content, microbial growth, and other factors.

5 A well-known method for characterizing the presence of water is by water activity. Water activity is measured as the ratio between the vapor pressure of water in an enclosed chamber containing a food and the saturation vapor pressure of water at the temperature. Water activity indicates the degree to which water is bound and, subsequently, available to act as a solvent or participate in destructive chemical and  
10 microbiological reactions.

When the water activity is low, water is unavailable because it is tightly bound to surface polar sites through chemisorption. Water activity is defined as:

$$15 \quad a_w = \frac{p}{P_0}$$

where  $a_w$  is water activity,  $p$  is the partial pressure of water above the sample, and  $P_0$  is the vapor pressure of pure water at the same temperature (must be specified).

Another definition of water activity which is more thermodynamically appropriate  
is

$$20 \quad a_w = \frac{P_{eq}}{P_0}$$

where  $P_{eq}$  is the partial vapor pressure of water in equilibrium with the solution and  $P_0$  is the vapor pressure of pure water at the same temperature and pressure as the solution.

25 When a solute is added to water, water molecules are displaced by solute molecules and the ratio of the vapor pressures or  $a_w$  is altered. Entropy is also lowered as solute molecules become oriented to water molecules. As a result, water molecules are not as free to escape from the liquid phase and the vapor pressure is therefore decreased. This change is governed by Raoult's law, which states that the decrease in vapor pressure of a  
30 solution is equal to the mole fraction of its solute. Similarly the ratio of vapor pressures

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( $a_w$ ) is governed by the number of moles of solute ( $n_1$ ) and solvent ( $n_2$ ):

$$a_w = \frac{P}{P_0} = \frac{n_1}{n_1 + n_2}$$

5 Different solutes tie up or bind water to varying degrees depending on the nature of the solute, such as its level of dissociation, extent and nature of intramolecular binding, solubility and chemical components.

Further, a portion of total water content present in foods is strongly bound to specific sites on the chemicals that comprise the foodstuff. These sites may include the  
10 hydroxyl groups of polysaccharides, the carboxyl, amino groups of proteins, and other polar sites that may hold water by hydrogen bonding or other strong chemical bonds. In addition to strongly bound water molecules, some of the water in foods is usually bound less firmly but is still not available as a solvent for various water-soluble food component. Thus, water activity is low when water is tightly bound to surface polar sites through  
15 chemisorption. The sites can include hydroxyl groups of hydrophilic material which are effective in controlling water activity.

In the present invention water activity is significantly lower than water activity of similar products found in the candy bar industry. For example, candy bars usually have a water activity of 62% - 68% equilibrium relative humidity (ERH). The confectionery  
20 product of the invention, however, has at most only about a 60% ERH, and is preferably not greater than about 55% ERH.

Another measure of free water in foodstuffs can be provided by the amount of biological growth within the composition. In the present invention, the biological activity is less than about 100 ppm, preferably less than about 25 ppm, and most preferably less  
25 than 10 ppm.

Another distinctive feature of the present invention is the ability to reduce fat and calories in confectionery products. As a result of the present invention, a confectionery nougat product can be made which has little or no fat content. This product qualifies under industry standards to be referred to as Reduced Fat (which means the fat content is

reduced by 1/3) and as Low Fat (which means the fat content is reduced by 50%).

It is believed that at least some of the components useful according to the invention can be advantageously provided in the form of a shearform matrix, as that term is defined hereunder, as shearform matrix materials can exhibit significantly enhanced wettability because of a randomized structure resulting from flash-flow processing or shear mixing. In one embodiment, shearform matrix refers to the product prepared by a method of flash-flow processing, a method which mixes and conditions ingredients for intimate contacting and enhanced hydration.

One embodiment of the present invention may also include pre-flash-flow processing of certain ingredients prior to combining with other ingredients as set forth hereinabove. Pre-flash-flow processing is simply flash-flow processing of the ingredients which comprise either the hydrobinding component or the saccharide-based component. A saccharide material, e.g., polydextrose, can be pre-flash-flow processed, with or without one or more adjunct ingredients such as active ingredients in order to produce the feedstock which will then be combined with the hydrobinding component. Flash-flow processing results in increased surface area and increased solubility of the ingredients subjected thereto, and contributes to actual binding of the ingredients to each other.

It can be particularly preferred, however, to avoid flash-flow processing altogether through the use of the aforementioned low and high shear mixing processes. In this way, the added time and expense associated with flash-flow processing (or pre-flash-flow processing) can be avoided. The same qualities associated with the final product (e.g. shear-form matrix attributes, intimate mixing) can be attained through the use of the shear mixing methods as would be attained through the use of flash-flow processing.

As noted hereinabove, the hydrobinding component is an ingredient which imbibes, delivers and maintains water in an amount sufficient to functionalize the resulting mass. The water which is hydrobound does not separate and become a separate phase. Accordingly, the hydrobinding component cooperates with other ingredients to deliver and maintain water sufficient to functionalize the mass of ingredients, including those ingredients which have been subjected to flash-flow processing.

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Thus, a hydrobinding component can be hydrated and mixed with the saccharide-based component (the latter being in the form of a shear form matrix as a result of pre-flash-flow processing, or as a result of low or high-shear mixing) to form a functionalized hydrobound confectionery mass. The hydrobinding component can itself, if desired, also be subjected to pre-flash-flow processing prior to hydration in order to enhance wettability. It is often preferred to include a saccharide material with the hydrobinding component when it is subjected to either flash-flow processing or shear mixing. After combining the hydrated hydrobinding component and the saccharide-based component, moisture is readily imbibed and disseminated throughout the non-hydrated components and/or ingredients. Again, unlike prior art methods and confectionery compositions, additional moisture is not required to form a hydrated mixture. Thus, excess water is not present in the resulting mass.

Flash-flow processing can be advantageous in the present invention since it is useful for preparing ingredients to be easily and quickly hydrated. Another very important result of flash-flow processing is intimate mixing of the ingredients. Intimate mixing has traditionally been achieved by the use of water as a mixing medium. Flash-flow processing, however, intimately contacts ingredients and randomizes ingredient location and structure of the resulting matrix. Randomizing the structure can be thought of as opening the physical and/or chemical structure for hydration.

The term flash-flow has become recognized in the art as referring to a process which uses conditions of temperature and force to transform a solid feedstock to a new solid having a different morphological and/or chemical structure. The term flash-flow is described in commonly-owned U.S. Patents 5,236,734, issued August 17, 1993 and 5,238,696, issued August 24, 1993, as well as U.S. Patent 5,518,730, issued May 21, 1996; U.S. Patent No. 5,387,431, issued February 7, 1995; and U.S. Patent No. 5,429,836, issued January 4, 1995.

Flash-flow processing can be accomplished either by a flash-heat method or via the less preferred flash-shear method, as described further herein. In the flash-heat process, the feedstock is heated sufficiently to create an internal flow condition, which

permits internal movement of the feedstock at subparticle level, and to exit openings provided in the perimeter of a spinning head. The centrifugal force created in the spinning head flings the flowing feedstock material outwardly from the head so that it reforms with a changed structure. The force necessary to separate and discharge flowable feedstock is provided by centrifugal force and the force of the ambient atmosphere impinging on feedstock exiting the spinning head.

One apparatus for implementing a flash-heat process is a cotton candy fabricating type machine, such as the Eocene-floss model 3017 manufactured by Gold Medal Products company of Cincinnati, Ohio. Other apparatus which provides similar forces and temperature gradient conditions can also be used. In particular, a spinning machine developed and patented by Fuisz Technologies Ltd. of Chantilly, VA and patented under US 4,458,823 may be especially preferred.

In the flash-shear process, shearform matrix is produced by raising the temperature of the feedstock, which includes a non-solubilized carrier such as a saccharide material, until the carrier undergoes internal flow upon application of a fluid shear force. The feedstock is advanced and ejected while in internal flow condition, and subjected to disruptive fluid shear force to form multiple parts or masses which have a morphology different from that of the original feedstock.

The flash-shear process can be carried out in an apparatus which has means for increasing the temperature of a non-solubilized feedstock and means for simultaneously advancing it for ejection. A multiple heating zone twin screw extruder can be used for increasing the temperature of the non-solubilized feedstock. A second element of the apparatus is an ejector which reduces the feedstock to a condition for shearing. The ejector is in fluid communication with the means for increasing the temperature and is arranged at a point to receive the feedstock while it is in internal flow condition. See commonly-owned U.S. Patent No. 5,380,473, issued on January 10, 1995 and entitled Process for Making Shear-Form Matrix. Of the flash-heat and flash-shear processes herein described, flash-heat appears to be much more readily adaptable to the process of the invention. However, those skilled in the art may find that flash-shear methodology



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can be adjusted to their particular needs.

In flash-flow processing, the time during which the feedstock material is subjected to elevated temperature is very short. In the flash-heat method, the feedstock is subjected to elevated temperature usually for only tenths of a second, and in the flash-shear method the feedstock is subjected to elevated temperatures for a time on the order of seconds. This has specific benefits in situations when materials might be degraded or otherwise detrimentally affected by excessive exposure to heat.

The saccharide-based component feedstock for producing a shearform matrix includes a carrier material. The carrier material can be selected from material which is capable of undergoing both physical and/or chemical change associated with flash-flow processing. Materials which can be used as carrier materials in the feedstock include, for example, saccharide ingredients such as sucrose, corn syrup solids, polydextrose, and mixtures thereof.

Sugars can also be used as an ingredient in the feedstock. Sugars are those substances which are based on simple crystalline mono- and di-saccharide structures, i.e., based on C<sub>5</sub> (pentose) and C<sub>6</sub> (hexose) sugar structures. Sugars include sucrose, fructose, lactose, maltose, etc., and sugar alcohols such as sorbitol, mannitol, maltitol, etc.

Other materials which can be incorporated into the feedstock to enhance the shearform matrix include, for example, flavors, sweeteners, colorants, surfactants or emulsifiers, and oleaginous materials such as fats and oils. Any of the adjunct materials described herein above can be included in the preparation of a suitable shearform matrix.

It has now been further discovered that while preparation of a shearform matrix as a result of flash-flow processing as described above may often be desirable, the same attributes in the final product, e.g. intimate mixing, can also be attained by shear mixing, preferably high shear mixing, of the components making up the aforesaid feedstock prior to combining the thus prepared feedstock with the hydrobinding component, e.g. gum or gelatin. In some instances, a combination of flash-flow process and shear mixing may be advantageously utilized to produce the product of the invention. For example, certain ingredients making up the saccharide-based feedstock may be subjected to flash-flow

procedures (such as pre-flash-flow processing) in order to combine them. Once combined, then the feedstock can then be shear mixed with the hydrobinding component to produce the food and/or drug delivery system of the invention.

An especially preferred high-shear mixer is known as a Littleford FKM 1200.

5 This device provides high shear mixing by proximal shearing blades which are at right angles to one another. The shearing blades consist of "plowers" and choppers, both of which are utilized for high shear mixing action. While not wishing to be bound by any particular theory, it is believed that high shear action provides both mixing and heating at the localized points of blade contact with the mix ingredients, thereby resulting in  
10 excellent dispersibility without the undesired effects of lumping etc. Other high shear mixers (with one or more mixing blades), currently available or yet to be developed, are also contemplated by the method of the invention.

If desired, the high shear mixer can be further equipped with a jacket heater to provide the benefits of additional warming. A preferred temperature range is from about  
15 30 degrees C to about 60 degrees C, more desirably within the range of about 30 degrees to about 45 degrees C.

A preferred procedure for high shear mixing is as follows: The jacket heater on the high shear mixer

is first activated and allowed to warm to a temperature of about 40 degrees C. Next, the  
20 saccharide-based component and other dry ingredients, e.g. calcium carbonate, are fed through the open hopper and allowed to mix using the plowers. For an 18 pound mixture, for example, the device is first run for about 2 minutes. Any added fat, along with emulsifiers, and the liquid-based hydrobinding component (together with any flavorings, sweeteners and coloring) are then fed into the mixer, and the choppers or high shear  
25 blades are activated to further complete the mixing. During this time, the jacket temperature may be increased to within the range of about 50-60 degrees C, preferably about 58-60 degrees to assist in the mixing, especially if fat is present in the mixture. The mixer is then run for about 5-10 minutes more, perhaps longer, to complete the mixing of the saccharide-based component and the hydrobinding component. Once mixing is

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complete, the entire matrix is then emptied into an appropriate container for slicing, sorting and shipping etc., e.g. is extruded and cut into dosage size pieces.

In certain instances, the use of a low shear mixing apparatus can also provide the product of the invention. Of these, a Sigma mixer and/or Hobart industrial paddle mixer may be suitable. In one preferred embodiment, the dry ingredients (saccharide-based component and any additional materials) are mixed in a Sigma mixer until a good consistency is obtained. Separately, the liquid ingredients (hydrobinding components) are mixed in a Hobart mixer, and then added to the Sigma mixer with the dry ingredients. The whole mixture is then run in the Sigma mixer for about 3 minutes. Variations of the foregoing process are certainly within the scope of the invention, depending upon the characteristics of the individual ingredients, and the attributes desired within the final product.

Another method of formulating the product of the invention utilizes both high- and low-shear mixing apparatus. Dry ingredients such as corn syrup solids and sucrose (polysaccharide component) are first mixed together with other dry ingredients, e.g. calcium carbonate, as well as any fat-based component and any emulsifier(s), in a high shear mixer, preferably a Littleford FKM 1200, according to the procedure described above (plowers first, followed by shearing blades for about 5-10 minutes). Next, in a low shear mixer (e.g. Hamilton) the liquid ingredients, i.e., the hydrobinding component along with any sweeteners, flavorings, colors and if desired, vitamin D3 formulation dissolved in corn syrup, are mixed together for a few minutes. This resulting mixture is then added to the dry mix (which has now been transferred from the high shear mixer to another low shear mixer, e.g. Guittard). All ingredients are then mixed in this second low shear mixer for a few more minutes (~ 3 minutes), with the resulting mass then sent through an extruder for final processing such as slicing, sorting and shipping, etc.

In still another embodiment of the method of the invention, the polysaccharide component along with the calcium carbonate and vitamin D3 are first mixed together in the high shear mixer. The resulting formulation is then added to the extruder together with the liquid ingredients for final mixing, and extrusion. The extruder would of course

be of the type which is adapted to receive the liquid components.

Through the use of either flash-flow processing or shear mixing, or both, the need to cook the confectionery product of the present invention is thus eliminated.

For a better understanding of the present invention, together with other and further  
5 objects, the following examples and tables are provided to illustrate the unique methods of making a confectionery mass and products resulting therefrom. Unless otherwise specified, percentages of components in the compositions are given as percentage by weight (wt%). Also, unless otherwise indicated, all materials were obtained from commercial suppliers.

#### 10 EXAMPLE 1

A series of confectionery-type masses was prepared according to the invention, for the delivery of a bioassimilable calcium source, in this case powdered calcium carbonate. The hydrobinding material was selected to be a mixture of medium weight gelatin (250 Bloom) and gum arabic. The saccharide-based material was selected to be sucrose (6X)  
15 or a mixture of sucrose and corn syrup solids. The components and the preparation conditions for these batches are given below in Table 1.

In this series of batches, the gelatin and gum arabic were premixed with glycerin. Then a controlled amount of water was added thereto, along with flavoring and color. The calcium carbonate and the saccharide-based material (corn syrup solids and sucrose)  
20 were added to a Littleford FKM-1200 high shear mixer. The mixer was then operated for 2 minutes using the plowers only. The premixed fat/emulsifier/sorbitan mixture was added to the mixer. The hydrobinding material above (gelatin et al.) was also added, and the resulting mass was mixed with an FKM-1200 high shear mixer for approximately 5-10 minutes.

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TABLE 1					
MATERIAL (wt%)	BATCH 1A	BATCH 1B	BATCH 1C	BATCH 1D	BATCH 1E
Gelatin	1-5%	---->	---->	---->	---->
Gum Arabic	0.1-1%	---->	---->	---->	---->
Flavoring	0.1-1%	---->	---->	---->	---->
Water	5-10%	---->	---->	---->	---->
Glycerin (99%)	0.1-3%	---->	---->	---->	---->
Color	0.1-0.5%	---->	---->	---->	---->
Calcium Carbonate	28.57%	---->	---->	---->	---->
Sugar 6X	25-40%	25-40	60-70	25-40	25-40
Corn Syrup Solids	25-40%	25-40	--	25-40	25-40
Fat Solids	3-10%	---->	---->	---->	---->
Lecithin	0.1-1%	---->	---->	---->	---->
Sorbitan	0.1-1%	---->	---->	---->	---->
Kettle Temp	43° C	40° C	40° C	35° C	40° C
Dry Powder Temp	39° C	36° C	40° C	32° C	40° C
Fat System Temp	74° C	55° C	54° C	56° C	86° C
Binder Temp	45° C	44° C	44° C	45° C	48° C
Final Product Temp	39° C	50° C	40° C	42° C	43° C
Mixing Time (Min)	5	5	5	5	5
Mixing Speed (%)	40	40	40	60	60

All of these batches yielded products which were extruded and cut into pieces calculated to deliver about 500 mg of bioassimilable calcium. The products varied in the degree of tackiness to touch, but all were chewy, with more than acceptable mouthfeel with at most only a minor amount of chalky texture on chewing. Thus, a nougat product quite acceptable to consumers is produced 1) without driving off excess water, and 2) without cooking the material.

**EXAMPLE 2**

A nougat composition was prepared without cooking or removal of water. The ingredients set forth in Table 2-A were mixed using a high shear mixer for 5 min at 40-50 cycles/min.

<b>TABLE 2-A</b>	
<b>Ingredient</b>	<b>Percent of Composition</b>
Calcium Carbonate	28.75 wt%
Powdered Sugar	30-40 wt%
Corn Syrup Solids, DE 36	30-40 wt%
Fat Solids	3-8 wt%
Emulsifiers	0.1-1 wt%
<b>TOTAL</b>	<b>100 wt%</b>

This mixed composition was then mixed with colors and flavors in a Sigma mixer, again for 5 min at 40-50 cycles/min.

In a separate vessel, glycerin and a vegetable gum were mixed and stirred to smoothness. Water was added, and again the mixture was stirred to smoothness. Gelatin was then added along with flavoring and coloring, and the mixture was stirred for about 1 minute to thicken. This mixture was then warmed to about 50°C in a microwave oven, about 30-45 sec. The warmed mixture was added to the primary mixture, and stirred with the sigma mixer for about 5 min at 40-50 cycles/min. The final product composition is presented in Table 2-B.

<b>TABLE 2-B</b>	
<b>Ingredient</b>	<b>Percent of Composition</b>
Primary Mixture	80-90 wt%
Flavoring	0.1-1 wt%

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TABLE 2-B	
Coloring	0.1-1 wt%
Glycerin	0.5-3 wt%
Vegetable Gum	0.1-1 wt%
Water	5-10 wt%
Gelatin	1-5 wt%
TOTAL	100 wt%

The resulting mass was removed from the mixer, and rolled to the desired thickness, e.g., about 3 cm. This product was completely homogeneous, and had a chewy texture.

### EXAMPLE 3

Another chewy nougat product was made using the same materials and proportions described in Example 1, except that the components described there as being part of the primary mixture were processed together using flash flow processing (described in the specification as pre-flash flow processing) to provide a shearform matrix. This shearform matrix was then added to the coloring and flavoring, and used as described. Again, the resulting product was homogenous, chewy in texture, and flavorful.

### EXAMPLE IV

The primary mixture prepared according to the method described in Example 1 was used to make a gelatin-free confection product suitable for use as a calcium supplement. The primary mixture, together with flavorant, colorant, and an artificial sweetener, were mixed together in a kettle for 5 min. Potassium citrate was then dissolved in water with warming to ~ 85 degrees C. The hot solution was immediately added to a mixture of locust bean gum, carrageenan, and glycerin in a beaker and mixed, to provide a warm paste. This paste was then added to the pre-mixed primary mixture, and mixed for about 5 min. The final temperature of the resulting nougat was ~50

degrees C. The amounts of the ingredients in this chewy nougat confection are given in Table 3.

TABLE 3	
Ingredient	Percent of Composition
Primary Mixture	85-95 wt%
Flavoring	1-3 wt%
Coloring	0.001 wt%
Aspartame	0.009 wt%
Locust Bean Gum	0.1-1 wt%
Carrageenan	0.1-1 wt%
Glycerin	2-7 wt%
Potassium Citrate	0.1-1 wt%
Potable Water	2-7 wt%
<b>TOTAL</b>	<b>100 wt%</b>

This pleasant-tasting and chewy gelatin-free nougat material was cut into approximately 5.3 g pieces, each of which provided 500 mg of calcium.

#### EXAMPLE 5

An additional chewy nougat product was made according to the method set forth in Example 1 which delivered 500 mg of calcium and 200 I.U.'s of vitamin D3 in both chocolate and mint flavors as follows:



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TABLE 4	
Ingredient	Percent of Composition
Calcium Carbonate	23.7%
Corn Syrup Solids	18.1-27.1%
6X Powdered Sugar	26.6-35.6%
Additional Corn Syrup Solids	2.6-3.0%
Fat Solids (Paramount B)	5.9%
Lecithin 3F UB	0.35%
Emulsifier (DurEm 117)	0.25%
Sorbitan Stearate (Sorbitan 60K)	0.25%
Vitamin D3*	2%
Glycerin	3.0%
Gum Arabic	0.4%
Gelatin (250 Bloom)	1.5-1.8%
Water	6-7%
Flavorings**	0.64-1.2%
Coloring	0.01%
Acesulfame K (Hoechst)	0.10%

\*Vitamin D3 was dissolved in a small amount of corn syrup and added with the liquid components.

\*\*Flavorings included the following: Peppermint, Spearmint, Vanilla, Cream, Chocolate, and Cocoa Powder.

### CONSUMER TASTE PREFERENCES

A mint-flavored chewy nougat formulation according to the foregoing embodiment was compared with three leading commercially-available (store bought) calcium supplement preparations in a random taste test. 100 consumers between the ages of 30 – 70 were chosen to participate and evaluate a total of four products according to the

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following criteria on a scale of 1 - 9: bite, firmness, flavor, sweetness, chewiness, melt, stickiness, juiciness, grit, aftertaste and coolness (the higher the score, the more positively the consumer judged each attribute). Each consumer was given an identical bite-size serving of each one of the four products in the same order (with crackers and a sip of water in between each serving). Consumers were not told the source or identity of the products they were evaluating, other than that each was a calcium supplement. Results are indicated below:

PRODUCT	PRODUCT A	PRODUCT B	PRODUCT C	INVENTION
BITE	5.95	3.78	4.11	6.49
FIRM	6.11	4.24	4.49	6.43
FLAVOR	5.65	4.43	4.81	6.57
SWEET	5.89	4.65	5.49	6.35
CHEW	6.41	3.78	4.00	5.81
MELT	5.62	4.65	4.43	5.86
STICK	5.22	4.95	4.81	4.81
JUICINESS	5.19	4.57	4.35	5.81
GRIT	6.27	3.59	3.22	5.84

PRODUCT	AFTERTASTE	COOLNESS
Product A	6.49	6.38
Product B	4.89	4.97
Product C	4.92	5.78
Invention	6.41	6.46

**EXAMPLE 6**

A health bar was prepared containing powdered dried whole carrot and zucchini as using low shear mixing as follows:

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TABLE 5		
Ingredient Number	Ingredient	Percent of Composition
1	Maltrin M-180	17.10
2	Corn Syrup Solids 36 DE	15.00
3	Corn Bran Fiber	3.00
4	Calcium Carbonate	1.50
5	Apple Powder	2.40
6	Carrot Powder	17.04
7	Zucchini Powder	3.18
8	MCT Oil (Neobeem-5 from Stepan)	0.60
9	Vanilla Powder 10X	0.06
10	Cream S.D. 307737	0.22
11	Yogurt Spray Dried	1.00
12	Glycerine 99%	10.00
13	Lecithin 3F-UB	0.30
14	High Fructose Corn Syrup 55	8.00
15	Fat Replacer (Date/Grape/Plum Flavoring)	10.00
16	Crisp Rice 102	10.00
17	Cinnamon Butter Flavor	0.60

5 In a Hobart mixer, ingredients 1 – 11 were mixed for 5 minutes at Speeds 1 and 2. Preblended mixes of ingredients 12 and 13 were then mixed in for 1 minute, and ingredients 14 and 15 were then added to the resulting mix and further blended for 1 minute. Ingredients 16 and 17 were next added and mixed for 1 minute. The resulting mass was removed from the mixer, laid down on a flat surface and rolled to a fairly uniform ½ inch thickness. The mixture was allowed to set at room temperature, and then cut into single serving bars. (If desired, the resulting bars can then be coated with a commercial yogurt preparation.)

Thus, while there have been described what are primary believed to be the preferred embodiments, those skilled in the art well appreciate that other and further changes and modifications can be made without departing from the true spirit of the invention, and it is intended to include all such changes and modifications within the scope of the claims which are appended hereto.

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**WE CLAIM:**

1. A method of making a confectionery mass comprising:  
combining a saccharide-based component and a hydrated hydrobinding component by shear mixing, and further combining at least one biologically active agent in said mass by adding said active ingredient to one of said saccharide-based component, said hydrated hydrobinding component, and said combination.
2. A method according to Claim 1, wherein said shear mixing is at least one member selected from the group consisting of high shear mixing and low shear mixing.
3. A method according to Claim 2, wherein said confectionery mass is unspun having the attributes of shearform matrix.
4. A method according to Claim 2, wherein said shear mixing is high shear mixing.
5. A method according to Claim 2, wherein said shear mixing is low shear mixing.
6. A method according to Claim 1, wherein said hydrobinding component comprises one or more ingredients selected from the group consisting of a food grade gum and gelatin.
7. A method according to Claim 1, wherein said saccharide-based component comprises a saccharide material selected from the group consisting of sucrose, corn syrup solids, polydextrose, and mixtures thereof.
8. A method according to Claim 1, wherein said saccharide-based component further comprises an oleaginous material, an emulsifier, or a mixture thereof.
9. A method according to Claim 3, wherein said active ingredient comprises a bioassimilable source of calcium.
10. A confectionery mass, comprising a fully functionalized hydrobound mass having substantially no phase separation of moisture, said confectionery mass comprising a saccharide-based component and a hydrobinding component in unspun shearform matrix.
11. A confectionery mass according to Claim 10, which further comprises confectionery ingredients hydrated sufficiently to provide said functionalized hydrobound mass.
12. A confectionery mass according to Claim 11, wherein said hydrobinding

component comprises at least one member selected from the group consisting of proteinaceous material and food grade gums and said saccharide-based component comprises a saccharide material selected from the group consisting of sucrose, corn syrup solids, polydextrose, and mixtures thereof.

13. A confectionery mass according to Claim 12, further comprising an active ingredient, wherein said active ingredient is a bioassimilable source of calcium.

14. A confectionery mass according to Claim 13, wherein said shearform matrix is unspun as a result of at least one method selected from the group consisting of high and low shear mixing.

15. An edible vegetable-based composition, comprising a functionalized hydrobound confectionery mass comprising a saccharide-based component, a hydrobinding component and one or more vegetable components, said confectionery mass being in shearform matrix and unspun as a result of high or low shear mixing.

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 98/10869

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A23G3/00 A23G3/02

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 0 155 203 A (NABISCO BRANDS INC) 18 September 1985 see abstract see page 1, line 9 - page 2, line 3 see page 25 see examples ---	1,2,4-7 3,8,9
X	US 5 587 198 A (CHERUKURI SUBRAMAN R ET AL) 24 December 1996 see the whole document ---	1-15
X	EP 0 753 296 A (AMERICAN HOME PROD) 15 January 1997 see examples 1,2,5 ---	1,2,4,6, 7,9
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
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- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

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PCT/US 98/10869

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 601 965 A (FUISZ TECHNOLOGIES LTD) 15 June 1994 see abstract see page 3, line 20 - page 5, line 36 ---	1-15
A	US 5 654 003 A (FUISZ RICHARD C ET AL) 5 August 1997 see the whole document ---	1-15
A	US 5 518 730 A (FUISZ RICHARD C) 21 May 1996 see the whole document ---	1-15
A	EP 0 679 339 A (FUISZ TECHNOLOGIES LTD) 2 November 1995 see the whole document ---	1-15
A	EP 0 685 170 A (MONSANTO CO) 6 December 1995 see page 2, line 26 - page 4, line 45 ---	1,2,4,6, 9
A	ANON.: "Manufacture of gum confectionery without boiling" SÜSSWAREN, vol. 26, no. 9, 1982, pages 271-276, XP002076357 -----	



# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/10869

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0155203 A	18-09-1985	AU 586417 B AU 3892885 A CA 1246929 A DE 3585291 A IN 164120 A IN 166719 A JP 60188027 A	13-07-1989 21-08-1986 20-12-1988 12-03-1992 14-01-1989 14-07-1990 25-09-1985
US 5587198 A	24-12-1996	AU 5883796 A CA 2195319 A CZ 9700279 A EP 0776168 A JP 10503660 T WO 9638049 A	18-12-1996 05-12-1996 11-06-1997 04-06-1997 07-04-1998 05-12-1996
EP 0753296 A	15-01-1997	AU 5588196 A BR 9602759 A CA 2178691 A CZ 9601703 A EA 960028 A HU 9601619 A JP 9002949 A NO 962490 A PL 314731 A SK 74496 A	02-01-1997 22-04-1998 14-12-1996 16-04-1997 31-12-1996 28-02-1997 07-01-1997 16-12-1996 23-12-1996 09-04-1997
EP 0601965 A	15-06-1994	US 5380473 A AU 670625 B AU 4917093 A CA 2108832 A DE 69313418 D DE 69313418 T DK 601965 T JP 7308564 A MX 9306622 A PL 300831 A	10-01-1995 25-07-1996 05-05-1994 24-04-1994 02-10-1997 26-03-1998 29-09-1997 28-11-1995 29-04-1994 16-05-1994
US 5654003 A	05-08-1997	US 5387431 A US 5501858 A CA 2141909 A	07-02-1995 26-03-1996 11-08-1995

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/10869

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5654003 A		CN 1119934 A	10-04-1996
		EP 0667147 A	16-08-1995
		JP 8038138 A	13-02-1996
		AT 168243 T	15-08-1998
		AU 663526 B	12-10-1995
		AU 2719192 A	29-04-1993
		CA 2081248 A	26-04-1993
		DE 69226237 D	20-08-1998
		EP 0540460 A	05-05-1993
		FI 924787 A	26-04-1993
		HU 65679 A	28-07-1994
		IL 104766 A	18-06-1996
		JP 5331073 A	14-12-1993
		MX 9206165 A	01-08-1993
		PL 172691 B	28-11-1997
		PL 173512 B	31-03-1998
		US 5422136 A	06-06-1995
		US 5429836 A	04-07-1995
		US 5427804 A	27-06-1995
		US 5597608 A	28-01-1997
		US 5472731 A	05-12-1995
		US 5709876 A	20-01-1998
		AU 3844993 A	18-11-1993
		CA 2095776 A	13-11-1993
		EP 0570327 A	18-11-1993
		JP 6048920 A	22-02-1994
		MX 9302783 A	31-05-1994
		US 5728397 A	17-03-1998
US 5518730 A	21-05-1996	AU 665844 B	18-01-1996
		AU 4405893 A	30-12-1993
		CA 2137268 A	09-12-1993
		EP 0746342 A	11-12-1996
		JP 7507548 T	24-08-1995
		WO 9324154 A	09-12-1993
EP 0679339 A	02-11-1995	US 5456932 A	10-10-1995
		AU 695360 B	13-08-1998
		AU 1761495 A	02-11-1995
		CA 2147020 A	23-10-1995

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/10869

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0679339 A		JP 8038075 A	13-02-1996
		US 5503862 A	02-04-1996
EP 0685170 A	06-12-1995	US 5534286 A	09-07-1996

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